



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, Maryland 20892-6910  
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500  
Bethesda, Maryland 20817  
Telephone: (301) 496-7163  
Facsimile: (301) 402-7065

December 16, 2019

Re: Animal Welfare Assurance  
A3255-01 [OLAW Case 2G]

Dr. Christopher S. Brown  
Institutional Official  
Vice President for Research  
University of Alabama- Birmingham  
1720 2<sup>nd</sup> Ave. S, 720C  
Birmingham, AL 35294-0107

Dear Dr. Brown,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 10, 2019 letter reporting three instances of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Alabama at Birmingham, following up on an initial telephone report on September 27, 2019. According to the information provided, OLAW understands the following about the incidents, which all occurred in the same laboratory, and the corresponding corrective actions:

- 1) Expired drugs were mixed with in-date ones and may have been given to nonhuman primates.
- 2) An unapproved detergent agent was used to clean animal skin. No adverse events were reported with the animals.
- 3) Drugs logs were filled out at a later time following administration and were incomplete. The animals did receive all medications as per protocol.

Corrective actions: All laboratory staff was counseled and retrained, expired drugs were stored separately, the Principal Investigator (PI) and staff must complete training in pain management in laboratory animals, the PI must submit a corrective action plan to the Institutional Animal Care and Use Committee (IACUC), and the laboratory was placed under enhanced post approval monitoring.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.  
Deputy Director  
Office of Laboratory Animal Welfare

cc: IACUC Chair  
Director IACUC  
Robert Gibbens, D.V.M., USDA-APHIS-AC

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Retrieved from Animal Research Laboratory Overview (ARLO)

**UAB THE UNIVERSITY OF ALABAMA AT BIRMINGHAM**  
Institutional Animal Care and Use Committee (IACUC)

December 10, 2019

Brent Morse, D.V.M.  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
6705 Rockledge Drive  
RKL1, Suite 360, MSC 7982  
Bethesda, Maryland 20892-7982  
Assurance # A3255-01

Dear Dr. Morse:

Below are descriptions of unapproved deviations from the Guide for the Care and Use of Laboratory Animals and/or the PHS Policy identified and discussed during the October (2019) IACUC full committee meeting. The incident of non-compliance was reported to the IACUC by a UAB employee and involved a single investigator. Described corrective actions are also included.

1. Several expired non-controlled compounds were found intermingled with "in date" compounds that could be potentially administered to non-human primates. Policy requires expired compounds to be stored separately from in date substances for proper disposal and assurance that the expired item is not mistakenly used. No evidence was found that expired items were administered to animals; however, this possibility could not be ruled out.
2. Use of an unapproved cleaning agent. The laboratory purchased and used a detergent for cleaning topical areas on animals when a more appropriate clinical use product should have been obtained for this purpose. No animal welfare issues were noted due to the use of this product.
3. Drug administration logs were not being filled out completely or were being entered at later time points than following administration. This led to missing information and reconstructive errors in the logs even though it appears that all medications were administered following the investigator's approved protocol.

The described incidents of non-compliance did not involve work funded by any NIH grant funds.

Corrective actions include all laboratory members were counseled on processes, and required remedial training. The PI is required to provide an action plan to the IACUC describing remediation for each non-compliance item. The IACUC will conduct at least two unannounced audits of the laboratory for the next 12 months, and the PI and staff must complete training in Pain Management in Laboratory Animals.

If you require additional information or clarification, please do not hesitate to let me know.

Sincerely,

 (b) (6)

Christopher S. Brown, Ph.D.  
Institutional Official and Vice President for Research

cc: Samuel C. Cartner, D.V.M., Ph.D., ARP Director  
Robert A. Kesterson, Ph.D., IACUC Chair  
David Cannon, B.A., C.P.I.A., IACUC Director  
AAALAC International

Institutional Animal Care and Use Committee  
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**Wolff, Axel (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, December 13, 2019 10:01 AM  
**To:** Cannon, David Grove  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: OLAW A3255-01 noncompliance report

Thanks Dave. We'll send a reply soon.  
Axel Wolff

**From:** Cannon, David Grove <dgcannon@uab.edu>  
**Sent:** Friday, December 13, 2019 9:54 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** 'accredit@aaalac.org' <accredit@aaalac.org>; Cartner, Samuel Corbin <scartner@uab.edu>; Kesterson, Robert Allen <kesterson@uab.edu>; Brown, Christopher <csbrown@uab.edu>  
**Subject:** OLAW A3255-01 noncompliance report

Dr. Morse,

Attached is the UAB IACUCs follow-up noncompliance Final incident report for Assurance A3255-01 sent on behalf of Christopher S. Brown, UAB's Institutional Official. These is one compliance issues. Please let me know if you have any questions that I can answer or provide additional clarity.

Sincerely,

David

David Cannon, CPIA | Director IACUC  
Institutional Animal Care and Use Committee  
UAB | University of Alabama at Birmingham  
(b) (4) | 933 19th St. South | Birmingham, AL 35294-2041  
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## Initial Report of Noncompliance

By: (b) (6)

Date: 9/27/19

Time: 4:00

Name of Person reporting: David Cannon

Telephone #: (b) (6)

Fax #: (b) (6)

Email:

Name of Institution: U of Alabama - Birmingham

Assurance number: A3255

Did incident involve PHS funded activity? \_\_\_\_\_

Funding component: \_\_\_\_\_

Was funding component contacted (if necessary): \_\_\_\_\_

What happened?

Expired drugs given to monkeys

Species involved: Monkeys, Baboons

Personnel involved:

Dates and times:

Animal deaths:

Projected plan and schedule for correction/prevention (if known): \_\_\_\_\_

Have EHS examine lab

Projected submission to OLAW of final report from Institutional Official:

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Case # \_\_\_\_\_